

Subchapter VIII — X-ray Device Requirements

HFS 157.74 Administrative requirements.

(1) **GENERAL.** The registrant shall be responsible for directing the operation of the x-ray systems under their administrative control. The registrant or the registrant's agent shall ensure the requirements of this section are met. An x-ray system shall meet the provisions of this subchapter to be operated for diagnostic or screening purposes. All images, hard copy or electronic, shall be interpreted by a licensed practitioner for the patient record.

(2) **RADIATION SAFETY REQUIREMENTS.**

(a) Each individual who operates x-ray equipment shall be instructed in the safe operating procedures for each specific device and be competent in the safe use of the equipment as determined by the registrant.

(b) A chart shall be available near the control panel of a diagnostic x-ray system that specifies, for all examinations performed with that system, all of the following information:

1. Patient's body part to be examined and anatomical size, body part thickness or, for pediatrics, age versus technique factors to be utilized.
2. Type and size of the film or film-screen combination to be used.
3. Type and focal distance of the grid to be used, if any.
4. Except for dental intra-oral radiography, source to image receptor distance to be used.
5. Type and location of placement of patient shielding to be used.

Note: This chart may be electronic in the form of pre-programmed controls.

(c) The registrant of a facility shall create and make available to x-ray operators written safety procedures, including patient holding procedures and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(d) Only the staff, ancillary personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure. Other than the patient, the following applies to all persons in the room:

1. All persons shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material. If the hands must be in the beam and unprotected, a ring badge on the hand in the beam shall be worn unless contraindicated by the clinical procedure.
2. All persons, including any patients who cannot be removed from the room, shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that all parts of the person's body are at least 2 meters from all of the following:
 - a. The tube head.
 - b. The direct beam.
 - c. The nearest part of the examined patient's body being struck by the useful beam.
3. Operators of c-arm configuration units which do not operate at a tube current in excess of 0.2 mA are exempt from the requirement to wear a leaded apron, provided the operator wears a personnel dosimeter as required under s. HFS 157.25 (2).

(e) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which the shielding would interfere with the diagnostic procedure or for computed radiographic examinations.

(f) Persons may not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. Deliberate exposure for any of the following purposes is prohibited:

1. Exposure of a person for training, demonstration or other non-healing arts purpose.
2. Exposure of a person for healing arts screening, except as authorized by the department.

Note: The procedure for requesting permission to conduct screening x-ray examination is in Appendix M.

(g) When a patient or film must be provided with additional support during a radiation exposure, all of the following applies:

1. The human holder shall be instructed in personal radiation safety and protected as required by subd. 2. Written safety procedures are required.
2. In those cases where the patient must hold the film, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
3. Each facility shall have leaded shielding garments and devices available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.
4. Leaded shielding garments and devices shall be fluoroscopically or radiographically inspected at least every 2 years for defects and replaced if defective. If visual inspection reveals possible defects, radiographic inspections shall be performed.

5. If visual inspection reveals possible defects, radiographic or fluoroscopic inspections shall be performed.

Note: Leaded shielding garments and devices include aprons, gloves, vests, skirts, thyroid shields and gonadal shields.

(h) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized, as follows:

1. The speed of the screen and film combinations used shall be of a speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens may not be used for any routine diagnostic radiological

imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. An x-ray system may not be utilized in a procedure where the source to patient distance is less than 30 centimeters, except for a veterinary system, bone density unit or a unit granted an exemption by the US food and drug administration.

4. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall meet all of the following requirements:

a. Be positioned with tube side facing the in right direction, and grid centered to the central ray.

b. Be of the proper focal distance for the SIDs being used. Grids shall be of the proper ratio to adequately reduce scatter for the procedure being performed.

c. Antiscatter grids or an appropriate air gap technique to reduce scatter to the image receptor shall be used for all x-ray examinations of the human torso utilizing stationary x-ray equipment for patients 12 years of age or older.

(i) All persons associated with the operation of an x-ray system are subject to the requirements of s. HFS 157.22 (1), (5), (7) and (8).

(j) A person proposing to conduct a healing arts screening program may not initiate a program without the department's prior approval. When requesting approval, the person shall submit the information outlined in Appendix M. If any information submitted to the department becomes invalid or outdated, the department shall be immediately notified.

(k) All facilities performing mammography shall meet the requirements of 21 CFR 900, US food and drug administration, Mammography Quality Standards Act.

(3) X-RAY FILM PROCESSING EQUIPMENT AND PROCESSING PROCEDURES.

(a) Each installation using a radiographic x-ray system for human diagnosis or screening and using analog image receptors shall have available suitable equipment for handling and processing radiographic film according to the film and chemistry manufacturer's instructions.

(b) Quality control and maintenance procedures shall be performed on a regular schedule according to the device manufacturer's recommendations.

(c) X-ray film processing control tests shall be performed and analyzed on days when human patient films are being processed and prior to the processing of the first films of the day, except dental and podiatry facilities. If analysis shows that the image quality has declined, corrective action shall be taken prior to processing patient films.

(d) X-ray film processors in dental and podiatry facilities shall be tested at least once a week.

(4) OTHER REQUIREMENTS.

(a) Pass boxes, if provided, shall be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

(b) The darkroom shall be light tight with proper safelights so that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to 2 when processed may not suffer an increase in density greater than 0.1, or 0.05 for mammography, when exposed in the darkroom for 2 minutes with all safelights on. This test shall be performed at least once every 6 months. If used, daylight film handling boxes shall preclude fogging of the film. Darkrooms typically used by more than one person shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

(c) Film shall be stored according to the manufacturer's requirements and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

(d) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary and consistent with the manufacturer's instructions to best assure radiographs of good diagnostic quality.

(e) Outdated x-ray film may not be used for diagnostic radiographs.

(f) Film developing solutions shall be prepared using instructions given by the manufacturer and maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021: am. (2) (b) (intro.), (g) 3., 4., (3) (c) and 4) (b), cr. (2) (d) 3. and (g) 5. Register October 2006 No. 610, eff. 11-1-06.

HFS 157.75 General requirements for all diagnostic x-ray systems. Diagnostic x-ray systems shall meet all the following requirements:

(1) WARNING LABEL. The control panel containing the main power switch shall bear the following warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) BATTERY CHARGE INDICATOR. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) LEAKAGE RADIATION FROM THE DIAGNOSTIC SOURCE ASSEMBLY. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source may not exceed one mGy (115 milliroentgens) in one hour when an x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. Leakage technique factors may be any of the following:

(a) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, which is 10 mAs, or the minimum obtainable from the unit, whichever is larger.

(b) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(c) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(4) RADIATION FROM COMPONENTS OTHER THAN THE DIAGNOSTIC SOURCE ASSEMBLY. The radiation emitted by a component other than the diagnostic source assembly may not exceed 20 μ Gy (2.15 milliroentgens) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) BEAM QUALITY.

(a) The half-value layer of the useful beam for a given x-ray tube potential may not be less than the values shown in Table HFS 157.75. If it is necessary to determine the half-value layer at an x-ray tube potential that is not listed in Table HFS 157.75, linear interpolation or extrapolation may be made.

TABLE HFS 157.75
HALF-VALUE LAYER REQUIREMENTS

Design Operating Range	Measured Operating Potential (kVp)	Half-Value Layer in mm Aluminum		
		Specified Dental Systems ¹	Specified Dental and Other Diagnostic X-Ray Systems ²	Other Diagnostic X-Ray Systems ³
Below 51	30	N/A	0.3	0.3
	40	N/A	0.4	0.4
51 to 70	50	1.5	0.5	0.5
	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.4
	80	2.3	2.3	2.8
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	4.1
	120	3.2	3.2	4.5
	130	3.5	3.5	5.0
	140	3.8	3.8	5.4
	150	4.1	4.1	5.9

¹ Dental intraoral systems manufactured after December 1, 1980.

² Dental intraoral systems manufactured on or before December 1, 1980.

³ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured as specified in federal x-ray equipment performance standards, 21 CFR 1020.

(b) For x-ray systems using capacitor discharge to provide power to an x-ray tube, half-value layer shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

(c) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently between the source and the patient.

(d) For x-ray systems with variable filtration controls, the system shall prevent an exposure unless the appropriate filtration is in place for the kilovolts peak selected.

(6) MULTIPLE TUBES. When 2 or more radiographic tubes are controlled by one exposure switch, the tube that has been selected shall be clearly indicated prior to initiation of the exposure. The indication shall be both on an x-ray control panel and at or near the selected tube housing assembly.

(7) MECHANICAL SUPPORT OF TUBE HEAD. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube-housing movement is a designed function of an x-ray system.

(8) TECHNIQUE INDICATORS.

(a) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors, which are set prior to the exposure, shall be indicated.

(b) The requirement in par. (a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(9) MAINTAINING COMPLIANCE. Diagnostic x-ray systems and their associated components used on humans and certified under the federal x-ray equipment performance standard, 21 CFR 1020, shall be maintained in compliance with applicable requirements of that standard.

(10) LOCKS. All position locking, holding and centering devices on x-ray system components and systems shall function as intended.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021:am. Table Register October 2006 No. 610, eff. 11-1-06.

HFS 157.76 Fluoroscopic equipment. Equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984, shall meet all the following requirements:

(1) LIMITATION OF USEFUL BEAM.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source to image distance. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The air kerma rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic image receptor shall not exceed 3.34×10^{-3} percent of the entrance air kerma rate, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(b) Compliance shall be determined as follows:

1. The air kerma rate shall be measured as required under sub.(4). The air kerma rate due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.
2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the source to image distance is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm.
3. Movable grids and compression devices shall be removed from the useful beam during the measurement.
4. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance air kerma rate and between this point and the input surface of the fluoroscopic imaging assembly.

(c) Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in 21 CFR 1020.30 (g).

(2) FIELD LIMITATION.

(a) For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with par. (e) 1. and 2. shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(b) Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of par. (e) 1. and 2. Beam limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable source to image distance and/or the capability of a visible area of greater than 300 square cm, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed source to image distance and the capability of a visible area of no greater than 300 square cm shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest source to image distance, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. This paragraph does not apply to nonimage-intensified fluoroscopy.

(c) The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest source to image distance, shall be containable in a square of 5 cm by 5 cm.

(d) For fluoroscopic equipment with inherently circular image receptors manufactured before June 10, 2006, other than radiation therapy simulation systems, all the following applies:

1. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3% of the source to image distance.

The sum of the excess length and the excess width shall be no greater than 4% of the source to image distance.

2. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(e) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation therapy simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform to one of the following requirements: 1. When any linear dimension of the visible area of the image receptor measured through the center of

the visible area is less than or equal to 34 cm in any direction, at least 80% of the area of the x-ray field overlaps the visible area of the image receptor.

2. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

(f) For x-ray systems with inherently rectangular image receptors manufactured on or after June 10, 2006, all the following applies:

1. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3% of the source to image distance. The sum of the excess length and the excess width shall be no greater than 4% of the source to image distance.

2. The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(g) If the fluoroscopic x-ray field size is adjusted automatically as the source to image distance or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(3) ACTIVATION OF TUBE. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

(4) AIR KERMA RATES. (a) Fluoroscopic equipment manufactured before May 19, 1995 shall meet all the following requirements:

1. Equipment provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 88 mGy per minute (10 R/min) at the measurement point specified in par. (e), except as specified in par. (e) 6.

2. Equipment provided without automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 44 mGy per minute (5 R/min) at the measurement point specified in par. (e), except as specified in par. (e) 6.

3. Equipment provided with both an automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 88 mGy per minute (10 R/min) in either mode at the measurement point specified in par. (e), except as specified in par. (e) 6.

4. Equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with par. (a). When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

Modified to comply with 21 CFR 1020.32 (h) (2).

(b) The requirements of par. (a) do not apply to all the following:

1. During recording of fluoroscopic images.

2. When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of the rates specified in this subsection at the measurement point specified in par. (e), unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(c) Fluoroscopic equipment manufactured on or after May 19, 1995 shall meet all the following requirements:

1. Equipped with automatic exposure rate control if operable at any combination of tube potential and current that results in an air kerma rate greater than 44 mGy per minute (5 R/min) at the measurement point specified in this subsection. Provision for manual selection of technique factors may be provided.

2. Not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 88 mGy per minute (10 R/min) at the measurement point specified in par. (e)

(d) The requirements of par. (c) do not apply to all the following:

1. For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

2. For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image after termination of exposure. Such recording does not include images resulting from a last image-hold feature that are not recorded.

3. When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an air kerma rate in excess of 176 mGy per minute (20 R/min) at the measurement point specified par. (e). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(e) Compliance with par. (c) shall be determined as follows:

1. If the source is below the x-ray table, the air kerma rate shall be measured at 1 cm above the tabletop or cradle.
2. If the source is above the x-ray table, the air kerma rate shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
3. In a C-arm type of fluoroscope, the air kerma rate shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available source to image distance, provided that the end of the beam limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.
4. In a C-arm type of fluoroscope having an source to image distance less than 45 cm, the air kerma rate shall be measured at the minimum source to skin distance.
5. In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

6. Fluoroscopic radiation therapy simulation systems are exempt from this paragraph.

(5) INDICATION OF POTENTIAL AND CURRENT. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with 21 CFR 1020.30 (h) (3).

(6) SOURCE TO SKIN DISTANCE.

(a) Means shall be provided to limit the source to skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 cm.

(b) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

(7) FLUOROSCOPIC IRRADIATION TIME, DISPLAY, AND SIGNAL.

(a) Fluoroscopic equipment manufactured before June 10, 2006, shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative Irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(b) As an alternative to the requirements of par. (a), radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

(c) For x-ray controls manufactured on or after June 10, 2006, all of the following shall be provided for each fluoroscopic tube:

1. A display of the fluoroscopic irradiation time at the fluoroscopist's working position.
2. The display required in subd. 1. shall function independently of the audible signal described in sub. (4) and meet all the following requirements:
 - a. When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds.
 - b. The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.
 - c. Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.
 - d. A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least 2 seconds.

(8) MOBILE AND PORTABLE FLUOROSCOPES. Mobile and portable fluoroscopes shall incorporate an image intensifier.

(9) DISPLAY OF LAST-IMAGE-HOLD.

(a) Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display the last image following termination of the fluoroscopic exposure.

(b) For an LIH obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

(c) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

(d) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

(e) The predetermined or selectable options for producing the LIH radiograph shall be described in the information required by 21 CFR 1020.30 (h). The information shall include a description of any technique factors applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.

(10) DISPLAYS OF VALUES OF AIR KERMA RATE AND CUMULATIVE AIR KERMA. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the air kerma rate and cumulative air kerma. Each x-ray tube used during an examination or procedure shall meet all the following requirements:

(a) When the x-ray tube is activated and the number of images produced per unit time is greater than 6 images per second, the air kerma rate in mGy/min shall be continuously displayed and updated at least once every second.

(b) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

(c) The display of the air kerma rate shall be clearly distinguishable from the display of the cumulative air kerma.

(d)

1. The air kerma rate and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the referenced locations.

2. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in sub. (4) for measuring compliance with air kerma rate limits.

3. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

Note: The reference location is identified and described specifically in the information provided to users according to 21 CFR 1020.30 (h) (6) (iii).

(e) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(f) The displayed air kerma rate and cumulative air kerma shall not deviate from the actual values by more than ± 35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of air kerma rate and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021: r. and recr. Register October 2006 No. 610, eff. 11-1-06.

HFS 157.77 General purpose radiographic systems.

(1) BEAM LIMITATION.

(a) *Collimation.* The useful beam shall be limited to the area of clinical interest. This requirement is met if a positive beam-limiting device meeting manufacturer's specifications has been properly used or if evidence of collimation is shown on at least 3 sides or 3 corners of the film. Mammography systems are exempt from the collimation requirement.

(b) *General purpose stationary and mobile x-ray systems.* General purpose stationary and mobile x-ray systems, including veterinary systems other than portable, shall meet both of the following requirements:

1. Only x-ray systems provided with means for independent stepless adjustment of at least 2 dimensions of the x-ray field may be used.

2. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field may not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(c) *Stationary general purpose x-ray systems.* Stationary general purpose x-ray systems, both certified and non-certified, shall meet all the following requirements:

1. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2% of the SID and to indicate the SID to within 2%.

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

3. Field size dimensions and SIDs shall be specified in inches or centimeters and shall ensure that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(d) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(e) *Miscellaneous and veterinary x-ray systems.* X-ray systems other than those described in pars. (a) to (c), veterinary systems installed prior to the effective date of August 1, 2002, and all portable veterinary x-ray systems shall meet all of the following requirements:

1. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
2. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.
3. The requirements in subds. 1. and 2. may be met with a collimator system that meets the requirements for a general purpose x-ray system or, when alignment means are also provided, may be met with either of the following:
 - a. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed.
 - b. A beam-limiting device with multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID that each aperture is designed for and shall indicate which aperture is in position for use.

(2) RADIATION EXPOSURE CONTROL.

(a) Exposure initiation.

Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action. In addition, exposure may not be initiated when the timer is set to a "zero" or "off" position if either position is provided.

(b) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) Exposure termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(d) Manual exposure control. An x-ray control shall be incorporated into each x-ray system so that the operator may terminate an exposure at any time except for any one of the following:

1. Exposure of 0.5 second or less.
2. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(e) Automatic exposure controls. When an automatic exposure control is provided, it shall meet all the following requirements:

1. Indication shall be made on the control panel when this mode of operation is selected.
2. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses.
3. The minimum exposure time for all equipment other than field emission equipment shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater.
4. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure.
5. A visible signal shall indicate when an exposure has been terminated and manual resetting shall be required before further automatically timed exposures may be made.

(f) Exposure duration linearity. For systems having independent selection of exposure time settings, the average ratios of exposure to the indicated timer setting, in units of .001 mGy/s (mR/s), obtained at any 2 clinically used timer settings may not differ by more than 0.10 times their sum as expressed as: $(X_1 - X_2) < 0.1 (X_1 + X_2)$ where X_1 and X_2 are the average .001 mGy/s (mR/s).

(g) Exposure control location. The x-ray exposure control shall be placed so that the operator may view the patient while making any exposure and at least 3 feet from the end of the protective barrier.

(h) Operator protection, except veterinary systems. X-ray systems, excluding veterinary systems, shall meet all the following requirements to protect the operator during system use, as applicable:

1. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.
2. Mobile and portable x-ray systems used continuously for greater than one week in the same location shall meet the requirements of stationary systems.

3. Mobile and portable x-ray systems used for less than one week at the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection during exposures or a means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during the exposure.

(i) *Operator protection for veterinary systems.* All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protection during exposures or a means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly during exposures. Persons restraining the animal during radiography shall be protected with at least 0.5mm lead aprons and full coverage gloves or full coverage mittens containing not less than 0.5mm lead equivalent material. The exposure control may be foot operated.

(3) **SOURCE-TO-SKIN DISTANCE.** All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

(4) **AIR KERMA REPRODUCIBILITY.** When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of air kerma for both manual and automatic exposure control systems may not exceed 0.05. This requirement applies to clinically used techniques.

(5) **RADIATION FROM CAPACITOR ENERGY STORAGE EQUIPMENT IN STANDBY STATUS.** Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated may not exceed any of the following:

(a) A rate of 0.26mGy (0.03mR exposure) in one minute at 5 centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(b) An air kerma of 0.88 mGy (100mr/exposure) in one hour at 100 centimeters from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in one hour of 100 square centimeters with no linear dimension greater than 20 centimeters.

(6) **ACCURACY.** Deviation of measured technique factors from indicated values of kVp and exposure time may not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation may not exceed 10% of the indicated value for kVp and 10% of the time limit.

(7) **mA/mAS LINEARITY.** X-ray equipment that is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated shall meet all the following requirements:

(a) *Equipment having independent selection of x-ray tube current (mA).* The average ratios of exposure to the indicated milliamperes-seconds product obtained at any 2 consecutive tube current settings may not differ by more than 0.10 times their sum: $X_1 - X_2 < 0.10 (X_1 + X_2)$ where X_1 and X_2 are the average values obtained at any of 2 consecutive tube current settings or at 2 settings differing by no more than a factor of 2 where the tube current selection is continuous.

(b) *Equipment having a combined x-ray tube current-exposure time product selector, but not a separate tube current selector.* The average ratios of exposure to the indicated milliamperes-seconds product, in units of .001 mGy/mAs (mR/mAs), obtained at any 2 consecutive mAs selector settings may not differ by more than 0.10 times their sum: $X_1 - X_2 < 0.10 (X_1 + X_2)$ where X_1 and X_2 are the average values obtained at any 2 consecutive mAs selector settings, or at 2 settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(c) *Measuring compliance.* Determination of compliance shall be based on 10 exposures taken within a time period of one hour at each of the 2 settings. These 2 settings may include any 2 focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by an x-ray tube manufacturer.

(8) **ADDITIONAL REQUIREMENTS APPLICABLE TO CERTIFIED SYSTEMS ONLY.** A diagnostic x-ray system incorporating one or more certified components shall meet all of the following additional requirements that relate to that certified component or components:

(a) *Beam limitation for stationary and mobile general purpose x-ray systems.* Stationary and mobile general purpose x-ray systems shall meet all the following beam limitation requirements:

1. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer type of collimator is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.

(b) *Beam limitation and alignment on stationary general purpose x-ray systems equipped with PBL.* If PBL is being used, the x-ray system shall meet all of the following requirements:

1. PBL shall prevent the production of x-rays when either one of the following occurs:
 - a. The length or width of the x-ray field in the plane of the image receptor differs, except as permitted by manual override, from the corresponding image receptor dimensions by more than 3% of the SID.
 - b. The sum of the length and width differences, without regard to positive or negative mathematical sign, exceeds 4% of the SID.
2. Compliance for exposure lock-out shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no more than 5 seconds after insertion of the image receptor.
3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.
4. The PBL system shall be designed such that a change in image receptor causes the automatic return to PBL.

(c) *Beam limitation for portable x-ray systems.* Beam limitation for portable x-ray systems shall meet the beam limitation requirements for manual collimators.

(9) TUBE STANDS FOR PORTABLE X-RAY SYSTEMS. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021:r. and recr. (5) Register October 2006 No. 610, eff. 11-1-06.

HFS 157.78 Intraoral dental radiographic systems.

(1) GENERAL. In addition to the provisions of ss. HFS 157.74 and 157.75, the requirements in this section apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are contained in s. HFS 157.77.

(2) SOURCE-TO-SKIN DISTANCE. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than either one of the following:

- (a) 20 centimeters (8 inches) if operable above 50 kVp. Beam-limiting devices shall be lead lined.
- (b) 10 centimeters (4 inches) if operable at 50 kVp only. Beam-limiting devices shall be lead lined.

(3) BEAM LIMITATION. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the beam at the minimum SSD shall be contained in a circle having a diameter of no more than 7 centimeters.

(4) RADIATION EXPOSURE CONTROL. Intraoral radiographic systems shall meet all of the following exposure control requirements:

- (a) *Exposure initiation.* Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action. An exposure may not be made when the timer is set to a "zero" or "off" position if either position is provided.
 - (b) *Exposure indication.* Means shall be provided for visual exposure indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
 - (c) *Exposure termination.* Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero" except for panoramic systems that may pause during the exposure cycle.
 - (d) *Exposure control location and operator protection.* An x-ray system shall meet all the following requirements, as applicable, to ensure operator protection during use of the system:
 1. A stationary x-ray system shall have an x-ray exposure control that may be moved to a protected area so that the operator is required to remain in that protected area during the entire exposure. The exposure cord shall be of sufficient length to allow the operator to be at least 2 meters (6.5 feet) from the x-ray tube head and not in the direction the tube is pointed. The operator shall be able to determine when the exposure has completed either by audible tone or by visible signal.
 2. A mobile or portable x-ray system that is used for greater than one week in the same location, which is a room or suite, shall meet the requirements of stationary dental equipment.
 3. A mobile or portable x-ray system that is used for less than one week in the same location shall be provided with either a protective barrier at least 2 meters (6.5 feet) high for operator protection or means to allow the operator to be at least 2 meters (6.5 feet) from the tube housing assembly while making exposures.
- (5) REPRODUCIBILITY.** When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of air kerma may be no greater than 0.05 for any specific combination of selected technique factors.

(6) mA/mAS LINEARITY. X-ray equipment that is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40% to 100% of the maximum rated shall meet all of the following requirements:

- (a) *Equipment having independent selection of x-ray tube current.* The average ratios of air kerma to the indicated milliamperere-seconds product, in units of .001 mGy/mAs (mR/mAs), obtained at any 2 consecutive tube current settings may not differ by more than 0.10 times their sum: $X_1 - X_2 < 0.10 (X_1 + X_2)$ where X_1 and X_2 are the average values obtained at each of 2 consecutive tube current settings, or at 2 settings differing by no more than a factor of 2 where the tube current selection is continuous.
- (b) *Equipment having a combined x-ray tube current-exposure time product selector but not a separate tube current selector.* The average ratios of air kerma to the indicated milliamperere-seconds product, in units of .001 mGy/mAs (mR/mAs), obtained at any 2 consecutive mAs selector settings may not differ by more than 0.10 times their sum: $X_1 - X_2 < 0.10 (X_1 + X_2)$ where X_1 and X_2 are the average values obtained at any 2 consecutive mAs selector settings, or at 2 settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.
- (c) *Measuring compliance.* Determination of compliance shall be based on 10 exposures taken within a time period of one hour at each of the 2 settings. The 2 settings may include any 2 focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by an x-ray tube manufacturer.
- (7) **ACCURACY.** Deviation of technique factors from indicated values for kVp and exposure time, if time is independently selectable, may not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation may not exceed 10% of the indicated value for kVp and 10% for time.
- (8) **KVP LIMITATIONS.** Dental x-ray machines with a nominal fixed kVp of less than 50 kVp may not be used to make diagnostic dental radiographs of humans.
- (9) **ADMINISTRATIVE CONTROLS.**
- (a) Intraoral film holding devices shall be used.
- (b) The tube housing and the cone may not be hand-held during an exposure.
- (c) The tube shall be stationary during exposure, except for panoramic systems. Any oscillation of the tube head shall cease before exposure is made.
- History:** CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.79 Veterinary medicine x-ray systems.

- (1) **GENERAL.** The requirements of this section apply to all animal use x-ray systems used in veterinary practice and are in addition to other provisions in subchs. I and III.
- (2) **EQUIPMENT.**
- (a) The tube housing shall be electrically shock proof and of a diagnostic type. The x-ray tube may not be hand-held during exposures.
- (b) A device shall be provided to terminate the exposure after a preset time or exposure.
- (c) A deadman type of exposure switch shall be provided with an electrical cord of sufficient length so that the operator or the assistant, may stand out of the useful beam and at least 2 meters (6.5 feet) from the table during all x-ray exposures. A foot operated exposure switch may be used and this switch may be integrated into the table base or the foot switch may be on a 2 meter (6.5 feet) cord.
- (3) **OPERATING PROCEDURES.**
- (a) The operator shall stand at least 2 meters (6.5 feet) from the tube housing and the animal during radiographic exposures. The operator may not stand in the useful beam. Hand-held fluoroscopic screens may not be used. The tube housing may not be held by the operator. No person other than the operator may be in an x-ray room while exposures are being made unless another person's assistance is required.
- (b) During any application in which the operator is not located behind a protective barrier, the operator and any other persons in the room during exposures shall wear protective clothing consisting of a protective apron having a lead equivalent of not less than 0.5 millimeter unless measurements indicate otherwise.
- (c) Any person holding or supporting an animal or the film during radiation exposure shall wear protective gloves that surround the hand and a protective apron having a lead equivalent of not less than 0.5 millimeter. Devices that only partially shield the hands are prohibited.
- (d) Veterinary fluoroscopy systems shall be operated only under the direct supervision of the licensed veterinarian.
- (4) **ANIMAL SUPPORT.** Mechanical restraints shall be used to restrict movement of the animal unless the restraints interfere with the examination of the animal. No persons may be regularly utilized to hold or support animals during radiation exposures. Operating personnel may not perform this service except in cases where no other person is available.
- History:** CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021:am. (2) (c) Register October 2006 No. 610, eff. 11-1-06.

HFS 157.80 Computed tomography x-ray systems.

- (1) **EQUIPMENT REQUIREMENTS.** A computed tomography (CT) x-ray system shall meet all of the following requirements, as applicable:
- (a) *Termination of exposure.* 1. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. The termination shall occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a back-up timer or devices which monitor equipment function. A visible signal shall indicate

when the x-ray exposure has been terminated. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

2. For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-ray with a shutter, the radiation emitted may not exceed 0.88 mGy (100mR) in 1 hour at any point 5 centimeters outside the external surface of the housing of the scanning mechanism when the shutter is closed.

3. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) *Tomographic plane indication and alignment.* A computed tomography x-ray system shall meet all of the following plane indication and alignment requirements, as applicable:

1. A single tomogram system shall allow for visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. A multiple tomogram system shall allow for visual determination of the location of a reference plane.

Note: The reference plane may be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy the requirements in subd. 2., the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(c) *Beam-on and shutter status indicators and control switches.*

1. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed. Each emergency button or switch shall be clearly labeled as to its function.

2. For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-ray with a shutter, the radiation emitted may not exceed 0.88 mGy (100 mRem) in one hour at any point 5 cm outside the external surface of the housing of the scanning mechanism when the shutter is closed.

3. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(d) *Indication of CT conditions of operation.* A CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of the scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(e) *Maximum surface CTDI100 identification.* The angular position where the maximum surface CTDI100 occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(f) *CT x-ray systems containing a gantry manufactured after September 3, 1985.* A computed tomography x-ray system containing a gantry that was manufactured after September 3, 1985, shall meet all the following requirements:

1. The total error in the indicated location of the tomographic plane or reference plane may not exceed 5 millimeters.

2. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment may not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this patient support device movement distance.

4. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(2) OPERATING PROCEDURES.

(a) A CT x-ray system may only be operated for diagnostic procedures by an American registry of radiologic technologists certified person who has been specifically trained in its operation. Combination systems which are designated as PET/CT shall be operated by a person qualified by training in the safe use of radioactive materials and who meets the training requirements of Appendix L.

(b) Information shall be available at the control panel regarding the operation and calibration of the system. The information shall include all of the following components:

1. Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

2. Instructions on the use of the CT dosimetry phantom including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent spot checks conducted on the system.

3. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized.

4. A current technique chart available at the control panel, which specifies for each routine examination the CT conditions of operation and the number of scans per examination including body part size and correct kV/mA for that body part. The technique chart shall be used to adjust techniques based on the body part being examined.

(c) Calibration and spot check measurements shall be made at a frequency recommended by the manufacturer. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance

established by the medical physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the medical physicist.

(d) A facility shall follow the manufacturer's daily start up routines and preventative maintenance schedules for a specific computed tomography x-ray system.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021:renum. (1) (a) and (c) to be (1) (a) 1. and (c) 1., cr. (1) (a) 2. and 3. and (c) 2. and 3., am. (2) (a) Register October 2006 No. 610, eff. 11-1-06.

HFS 157.81 Shielding plan review. (1) PLAN REVIEW AND APPROVAL. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be submitted to the department for review and approval.

Note: Plans may be mailed to the department at: Department of Health and Family Services, Radiation Protection Section, P.O. Box 2659, Madison WI 53701-2659 or package delivery to: Department of Health and Family Services, Radiation Protection Section, Room 150, 1 West Wilson St, Madison WI 53702-0007.

(2) EXEMPTIONS. Dental, mammography, and bone density devices are exempt from this section.

(3) PLAN SUBMITTAL REQUIREMENTS.

(a) A shielding plan for a facility with two or more x-ray rooms shall include a medical physicist or person approved by a medical physicist recommendation for shielding.

(b) A shielding plan submitted for department review shall include all of the following:

1. The maximum rated technique factors of each machine.
2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by a person in such areas. In addition, the drawing shall include all of the following:
 - a. The type and thickness of materials, or lead equivalency, of each protective barrier.
 - b. The use and occupancy of the areas surrounding an x-ray room, including occupied areas above or below an x-ray room.
 - c. The construction materials used for the floor and ceiling, if appropriate.

(c) . The operator booth described in the shielding plan shall be designed to meet all the following requirements:

1. The view area of the window shall be at least 0.09 m² (144 square inches).
2. The window shall be placed so that the edge of the view window is at least 0.45 meters (18 inches) from the end of the barrier. The window shall be placed so that the patient may be observed at all times and each entrance to the room is observed from the operator position. Patient and entrance observation may be accomplished by the use of electronic devices or mirrors.
3. The shielding value of the window shall be equal to the wall in which it is mounted.
4. Booth walls shall be 2.1 meters (7 feet) in height and permanently attached to the floor or walls. The booth shall be at least 1.3 meters (4 feet) from the nearest vertical cassette holder or 0.3 meters (one foot) from the nearest corner of the examining table.
5. When a door or moveable panel is used as an integral part of the booth structure, it shall have a permissive device that prevents an exposure when the door or panel is not closed.
6. Verbal communication with the patient shall be possible at all times during the x-ray procedure.

(4) OPERATIONAL ANALYSIS. The department may require additional modifications to a shielding plan after initial approval of the plan if a subsequent analysis of operating conditions indicates the possibility of a person receiving a dose in excess of the limits prescribed in ss. HFS 157.22 (1) and (5) to (8) and 157.23 (1) and (2). An existing x-ray room constructed using 5 mSv (500 mR) as the public exposure limit may continue to operate without modification until the x-ray equipment is replaced or the room is modified.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021:am. (3) (a) Register October 2006 No. 610, eff. 11-1-06.

HFS 157.82 General administrative requirements for facilities using therapeutic radiation machines for human use.

(1) ADMINISTRATIVE CONTROLS. A registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the department. All persons operating a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the radiation safety requirements of ss. HFS 157.22 (1) and (5) to (8) and 157.25 (2). A therapeutic radiation machine that does not meet the provisions of this subchapter but is of a type accepted by the US food and drug administration may not be used for irradiation of human patients.

(2) TRAINING FOR RADIATION THERAPY USERS.

(a) A registrant for any therapeutic radiation machine, except dermatology units under 150 kV, shall require the authorized user to be a physician who meets any of the following requirements:

1. Certified or board eligible in one or more of the following:
 - a. Radiology or therapeutic radiology by the American board of radiology.
 - b. Radiation oncology by the American osteopathic board of radiology.
 - c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology".
 - d. Therapeutic radiology by the Canadian royal college of physicians and surgeons.
2. Actively practices therapeutic radiology and has completed all of the following:

- a. The radiation therapy residency.
 - b. Two hundred hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit.
 - c. Five hundred hours of supervised work experience in therapeutic radiology.
 - d. A minimum of 3 years of supervised clinical experience or 5 years of post graduate clinical experience in therapeutic radiology.
3. Has equivalent training and submits the training of the prospective user physician for department review on a case-by-case basis.
 - (b) A dermatologist using x-ray units under 150 kV shall be board certified in dermatology or have 40 hours of instruction and 100 hours of supervised therapeutic work using x-ray units for the treatment of skin diseases.
- (3) VISITING USERS.** A registrant may permit any physician qualified under sub. (2) to act as a visiting user under the term of the registrant's registration for up to 60 days per year under all the following conditions:
- (a) The visiting user has the prior written permission of the registrant's management and if the use occurs on behalf of an institution, the institution's radiation safety committee.
 - (b) The registrant maintains copies of all records documenting the qualifications of the visiting user for 3 years from the date of the last visit.
- (4) MEDICAL PHYSICIST SUPPORT.**
- (a) The services of a medical physicist is required in facilities having one or more therapeutic radiation machines.
 - (b) The registrant for any therapeutic radiation machine shall require the medical physicist to have any of the following:
 1. Certification by the American board of radiology in one or more of the following:
 - a. Therapeutic radiological physics.
 - b. Roentgen-ray and gamma-ray physics.
 - c. X-ray and radium physics.
 - d. Radiological physics.
 2. Certification by the American board of medical physics in radiation oncology physics.
 3. Certification by the Canadian college of medical physics.
 4. A master's or doctor's degree in physics, biophysics, radiological physics or health physics and have completed one year of full-time training in therapeutic radiological physics and one year of full-time work experience under the supervision of a medical physicist at a medical institution. A person qualifying under this subdivision shall work under the supervision of a medical physicist qualified under subd. 1., 2. or 3. A registrant employing a physicist who qualifies under this subdivision shall provide the department with a statement of training and experience, signed by the preceptor medical physicist or provide a letter from another state accepting the person as a therapeutic medical physicist.
 - (c) The medical physicist shall be responsible for all of the following:
 1. Full calibrations and protection surveys.
 2. Supervision and review of dosimetry.

dosimetry and supervision of its use.

4. Quality control, including quality control check review.
5. Consultation with the physician user in treatment planning, as needed.
6. Performance of calculations and assessments regarding medical events.
7. Acceptance testing of the machine after any repair or service that may have altered the machine's performance characteristics.
- (d) If the medical physicist is not a full-time employee of the registrant, the operating procedures shall also specifically address how the medical physicist is to be contacted for problems or emergencies, as well as the specific actions to be taken until the medical physicist may be contacted.

(5) QUALIFICATION OF OPERATORS. (a) A person who will be operating a therapeutic radiation machine for medical use shall be an American registry of radiologic technologists registered radiation therapy technologist or a user authorized under sub. (2) or (3). A person who is not an ARRT registered radiation therapy technologist shall submit evidence that he or she has satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the joint review committee on education in radiologic technology.

Note: "Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988, establishes the requirements for a therapy technologist training program. The document is available at: <http://www.jrcert.org/>.

- (b) The names and training of all personnel currently authorized

to operate a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least 3 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

(6) SAFETY PROCEDURES. Written safety procedures and rules shall be developed by a medical physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(7) WRITTEN DIRECTIVE REQUIRED. Persons may not be exposed to the useful beam except for medical therapy purposes and unless exposure has been ordered in writing by a physician user qualified under sub. (2) or (3). This provision specifically prohibits deliberate exposure of an person for training, demonstration or other non-healing arts purposes.

(8) INFORMATION AND RECORDS. The registrant shall maintain all of the following information in a separate file or package for each therapeutic radiation machine for inspection by the department:

(a) Report of acceptance testing.

(b) Records of all surveys, calibrations and periodic quality control checks of the therapeutic radiation machine, as well as the names of persons who performed those activities.

(c) Records of maintenance or modifications performed on the therapeutic radiation machines, as well as the names of persons who performed these services.

(d) Signature of each person authorizing the return of a therapeutic radiation machine to clinical use after service, repair or upgrade.

(9) RECORD RETENTION. All records required by sub. (8) shall be retained for 3 years or until disposal is authorized by the department. Any required record generated prior to the last department inspection may be microfilmed or otherwise archived as long as a complete legible copy of the record may be retrieved.

History: CR 01-108; cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.83 Administrative policies and procedures for radiation therapy machines. (1) WRITTEN POLICIES.

A registrant shall have written policies and procedures to ensure that radiation will be administered as directed by an authorized user. The policies shall meet all of the following specific objectives:

(a) Prior to administration, a written directive is prepared for any external beam radiation therapy dose. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose. If, because of the patient's condition, a delay to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 24 hours of the oral revision.

(b) Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the person named in the written directive.

(c) External beam radiation therapy final plans of treatment and related calculations are according to the respective written directives.

(d) Each administration is according to the written directive.

(e) Any unintended deviation from the written directive is identified, documented, evaluated and appropriate action is taken.

(2) DEVELOPMENT OF THE OPERATIONAL PROCEDURES PROGRAM.

A therapy device registrant shall do all the following:

- (a) Develop an operational procedures program that specifies staff duties and responsibilities, and equipment and procedures. The registrant shall implement the program upon issuance of a certificate of registration by the department.
- (b) Develop procedures for and conduct a review of the program including, since the last review, an evaluation of a representative sample of patient administrations and all medical events to verify compliance with all aspects of the operational procedures program.
- (c) Conduct program reviews at intervals not to exceed 12 months.
- (d) Evaluate each of the reviews specified in par. (b) to determine the effectiveness of the program and, if required, make modifications to meet the requirements of par. (b).
- (e) Maintain records of each review specified in par. (b), including the evaluations and findings of the review, in an auditable form for 3 years.

(3) MEDICAL EVENTS. (a) A registrant shall report any of the following medical events:

- 1. A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue or 0.5 Sv (50 rem) shallow dose equivalent to the skin and any of the following exist:
 - a. The total dose delivered differs from the prescribed dose by 20% or more.
 - b. The fractionated dose delivered exceeds the prescribed dose, for a single fraction, by 50% or more.
- 2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue or 0.5 Sv (50 rem) shallow dose equivalent to the skin under any of the following conditions:
 - a. An administration of a dose to the wrong patient or human research subject.
 - b. An administration of a dose delivered by the wrong mode of treatment.
- 3. A dose to an organ outside the intended treatment volume that exceeds the expected dose to that organ by 0.5 Sv (50 rem) where the excess dose is greater than 50% of the expected dose to that organ.

(b) In response to a medical event, a registrant shall do all of the following:

- 1. Notify their department head no later than the next calendar day after discovery of the medical event.
- 2. a. Submit a written report to the department within 15 working days after discovery of the medical event. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian and if not, why not; and if the patient was notified, what information was provided to the patient.

Note: Mail the report to the Department at: Department of Health and Family Services, Radiation Protection Section, PO Box 2659, Madison WI 53701-2659.

- b. The report in subd. 2. a. may not include the patient's name or other information that could lead to identification of the patient.
- 3. Notify the referring physician and the patient of the medical event no later than 24 hours after the medical event's discovery, unless the referring physician personally informs the registrant either that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient of the medical event as soon as possible. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the medical event, because of any delay in notification.
- 4. Retain a record of each medical event for 3 years. The record shall contain all of the following:
 - a. The names of all persons involved.
 - b. The patient's unique identification number.
 - c. A brief description of the event, why it occurred and the effect on the patient.
 - d. What improvements are needed to prevent recurrence and the actions taken to prevent recurrence.
 - e. Whether the registrant notified the patient or patient's guardian and if not, why not, and if the patient was notified, what information was provided to the patient.
 - f. If information was not given to the patient at the direction of the referring physician, the reason why the information was not given to the patient.
- 5. If the patient was notified, furnish, within 15 working days after discovery of the medical event, a written report to the patient by sending either a copy of the report that was submitted to the department, or a brief description of both the event and the consequences as they may affect the patient, if a statement is included that the report submitted to the department may be obtained from the registrant.

(4) RIGHTS. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, patients or the patient's responsible relatives or guardians.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021:am. (2) (b) Register October 2006 No. 610, eff. 11-1-06.

HFS 157.84 Technical requirements for facilities using therapeutic radiation machines.

(1) RADIATION PROTECTION SURVEYS.

(a) A registrant shall ensure that radiation protection surveys of all new facilities and existing facilities not previously surveyed are performed with an operable, calibrated survey instrument. The radiation protection survey shall be performed by or under the direction of a medical physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation, all of the following requirements are met:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in s. HFS 157.22 (1) (a).

2. Radiation levels in unrestricted areas do not exceed the limits specified in s. HFS 157.23 (1) (a) and (b).

(b) A radiation protection survey shall be performed prior to any subsequent medical use after making any of the following changes:

1. Any change in the treatment room shielding.

2. Any change in the location of the therapeutic radiation machine within the treatment room.

3. Relocating the therapeutic radiation machine.

4. Using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(c) The survey record shall indicate all of the following:

1. Instances where the facility, in the opinion of the medical physicist, is in violation of applicable regulations.

2. The date of the measurements.

3. The reason the survey is required.

4. The radiation therapy machine manufacturer's name.

5. The model and serial number of the therapeutic radiation machine.

6. The instruments used to measure radiation levels and their last date of calibration.

7. A floor plan of the areas surrounding the treatment room that were surveyed.

8. The radiation level at several points in each area expressed in microsieverts or millirems per hour.

9. The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area.

10. The signature of the person responsible for conducting the survey.

(d) If the results of radiation protection surveys indicate any radiation levels in excess of the respective limit, the registrant shall lock the control in the "OFF" position and may not use the unit except under one or more of the following conditions:

1. As may be necessary to repair, replace or test the therapeutic radiation machine, the therapeutic radiation machine shielding or the treatment room shielding.

2. Until the registrant has received a specific exemption from the department.

(2) MODIFICATION OF RADIATION THERAPY UNIT OR ROOM BEFORE BEGINNING A TREATMENT PROGRAM. If the survey indicates that a person in an unrestricted area may be exposed to levels of radiation greater than those permitted by s. HFS 157.23 (1) (a) and (b), before beginning the treatment program, the registrant shall do all of the following:

(a) Equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with s. HFS 157.23 (1) (a) and (b).

(b) Perform the survey again.

(c) Include in the report the results of the initial survey, a description of the modification made and the results of the second survey.

(d) Submit facility design information to the department prior to installation of a therapeutic radiation machine of higher energy into a room not previously approved for that energy and receive approval from the department prior to actual installation of the therapeutic radiation machine.

(3) DOSIMETRY EQUIPMENT. (a) 1. A registrant shall have a calibrated dosimetry system available for use. The dosimetry system shall be calibrated by a certified calibration facility at least every 24 months and after any servicing that may affect system calibration.

2. For beams with energies greater than one MeV, the dosimetry system shall be calibrated for Cobalt-60.

3. For beams with energies equal to or less than one MeV, the dosimetry system shall be calibrated at an energy or energy range appropriate for the radiation being measured.

(b) A registrant shall have a dosimetry system for quality control check measurements. The system may be compared with another system whose calibration is traceable to the national institute of standards and technology. The comparison shall be performed at least every 24 months and after each servicing that may affect system calibration.

(c) A registrant shall maintain a record of each dosimetry system calibration, intercomparison and comparison for the duration of the registration. For each calibration, intercomparison or comparison, the record shall include all of the following:

1. The date.

2. The model and serial numbers of the instruments that were calibrated, inter-compared or compared.
3. The correction factors that were determined.
4. The names of the persons who performed the calibration, intercomparison or comparison.
5. Evidence that the intercomparison was performed by or under the direct supervision and in the physical presence of a medical physicist.

(4) SURVEY INSTRUMENTS. Except for dermatology offices with systems operating at less than 150 kV, each facility location authorized to use a therapeutic radiation machine shall possess appropriately calibrated portable monitoring equipment. Equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (one mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated.

(5) SHIELDING AND SAFETY DESIGN REQUIREMENTS.

(a) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted to the department and approved by the department prior to actual installation of the therapeutic radiation machine.

(b) Observation and communication with the patient shall be possible at all times.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.85 Therapeutic radiation machines.

(1) LEAKAGE RADIATION.

(a) When a therapeutic radiation machine is operated at its maximum dose rate, the leakage air kerma rate may not exceed the value specified at the distance specified for that classification of therapeutic radiation machine.

(b) Leakage radiation from contact therapy systems may not exceed one mGy (103 mR) per hour at 5 centimeters from the surface of the tube housing assembly. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which may be positioned over the entire useful beam exit port during periods when the beam is not in use.

(c) Leakage radiation from systems operating at 150 kV or less may not exceed one mGy (103 mR) per hour at one meter from the tube housing.

(d) Leakage radiation from systems operating above 150 kV may not exceed 0.1% of the useful beam one meter from the source housing for any of its operating conditions.

(2) PERMANENT BEAM-LIMITING DEVICES. Permanent, non-adjustable collimators used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) ADJUSTABLE OR REMOVEABLE BEAM-LIMITING DEVICES.

(a) All removable beam-limiting devices or diaphragms may not transmit more than one percent of the useful beam for the most penetrating beam used. This paragraph does not apply to beam shaping blocks or shaping materials.

(b) When adjustable beam-limiting devices are used, the position and shape of the useful beam shall be indicated by a light beam. These devices may transmit not more than 5% of the useful beam.

(4) FILTER SYSTEMS. The filter system shall be designed to meet all of the following requirements:

(a) Accidental displacement of filters is not possible at any tube orientation.

(b) If the proper filter is not in place, an interlock system shall prevent irradiation.

(c) The air kerma rate escaping from the filter placement opening slot in the tube head may not exceed 100 mGy (one rad) per hour at one meter under any operating conditions.

(d) Each filter shall be marked as to its material of construction and its thickness.

(e) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be reestablished.

(f) If the absorbed dose rate information relates exclusively to operation with a field flattening filter or beam scattering foil in place, that foil or filter shall be removable only by the use of tools.

(5) TUBE IMMOBILIZATION.

(a) An x-ray tube shall be mounted so that it cannot accidentally turn or slide with respect to the opening in the tube housing through which radiation is emitted.

(b) The tube housing assembly shall be capable of being immobilized.

(6) EMERGENCY SWITCHES. At least one emergency power cutoff switch shall be present. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality control checks of the emergency power cutoff switches may be conducted at the end of the treatment day to minimize possible stability problems with the therapeutic radiation machine.

(7) SOURCE MARKING. An x-ray tube housing assembly shall be marked so that it is possible to determine the location of the focal spot to within 5 millimeters and the marking shall be readily accessible for use during calibration procedures.

(8) TIMER.

(a) A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval or after a preset radiation dose has been delivered.

- (b) A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator.
- (c) A timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation may be reinitiated, it shall be necessary to reset the elapsed time indicator.
- (d) A timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.
- (e) A timer may not permit an exposure if set at zero.
- (f) A timer may not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer end effect correction to compensate for mechanical lag.
- (g) A timer shall be accurate to within one percent of the selected value or one second, whichever is greater.
- (9) CONTROL PANEL INDICATORS.** An x-ray unit shall have all of the following:
 - (a) An indication at the control panel of whether electrical power is on and if activation of the x-ray tube is possible.
 - (b) An indication of whether x-rays are being produced.
 - (c) A means for indicating x-ray tube potential and current.
 - (d) A means for terminating an exposure at any time.
 - (e) A locking device that will prevent unauthorized use of the therapeutic radiation machine.
- (10) TARGET TO SKIN DISTANCE.** There shall be a means of determining the central axis target to skin distance to within 2 millimeters and of reproducing this measurement to within 2 millimeters thereafter.
- (11) SHUTTERS.** Unless it is possible to bring the x-ray tube output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a shielding equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.
- (12) LOW FILTRATION MACHINES.** Each therapeutic radiation machine equipped with a beryllium or other low filtration window shall be clearly labeled on the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.
- (13) FULL CALIBRATION MEASUREMENTS.**
 - (a) Full calibration of a therapeutic radiation machine shall be performed by or under the direct supervision of a medical physicist under all of the following conditions:
 1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine.
 2. At intervals not exceeding 12 months.
 3. Before medical use under all of the following conditions:
 - a. Whenever quality control check measurements indicate that the radiation output differs by more than 5% from the value obtained at the last full calibration and the difference cannot be reconciled.
 - b. Following any component replacement, major repair or modification of components that could significantly affect the characteristics of the radiation beam.
 - (b) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those operational modes or radiation energies that are not within their acceptable range.
 - (c) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality control check procedures.
 - (d) Full calibration shall include all measurements recommended for annual calibration by protocols approved by recognized national or international organizations. An acceptable protocol is the "Protocol for clinical reference dosimetry of high-energy photon and electron beams" as stated in AAPM Report No. 67, American Association of Physicists in Medicine, 1999.

Note: Report No. 67 "Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams," was published in *Medical Physics*, 26 (9), September 1999, pp. 1847-70. The report may also be obtained from: Medical Physics Publishing, 4531 Vernon Blvd., Madison WI 53705-4964 or ordered from their website: www.medicalphysics.org.
 - (e) A registrant shall maintain a record of each calibration for the duration of the registration. The record shall include all of the following:
 1. The date of the calibration.
 2. The manufacturer's name, model and serial number for both the therapeutic radiation machine and the x-ray tube.
 3. The model and serial numbers of the instruments used to calibrate the therapeutic radiation machine.
 4. The signature of the medical physicist responsible for performing the calibration.
- (14) QUALITY CONTROL CHECKS.**
 - (a) Quality control checks shall be performed on therapeutic radiation machines.
 - (b) Quality control checks shall meet all of the following requirements:
 1. A registrant shall perform quality control checks using written procedures established by a medical physicist.
 2. The quality control check procedures shall specify all of the following:
 - a. The frequency at which tests or measurements are to be performed.
 - b. Which quality control checks are to be performed during calibration.

- c. The acceptable tolerance for each parameter measured in the quality control check when compared to the value for that parameter.
- (c) The cause for a parameter exceeding a tolerance set by the medical physicist shall be investigated and corrected before the system is used for patient irradiation.
- (d) Whenever a quality control check indicates a significant change in the operating characteristics of a system, as specified in the medical physicist's quality control check procedures, the system shall be recalibrated.
- (e) A registrant shall have the medical physicist review and sign the results of each radiation output quality control check within 10 working days of the date that the check was performed.
- (f) A registrant shall ensure that daily safety quality control checks of therapeutic radiation machines are performed.
- (g) Safety quality control checks shall be performed prior to the first treatment of the day to ensure proper operation of all of the following:
 1. Electrical interlocks at each external beam radiation therapy room entrance.
 2. The "BEAM-ON" and termination switches.
 3. Beam status indicator lights on the access doors, control console and in the radiation therapy room.
 4. Viewing systems.
 5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.
- (h) A registrant shall maintain a record of each quality control check for 3 years. The record shall include all of the following:
 1. The date of the quality control check.
 2. The manufacturer's name, model and serial number of the therapeutic radiation machine.
 3. The manufacturer's name, model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine.
 4. The signature of the person who performed the periodic quality control check.

(15) QUALITY CONTROL CHECKS FOR ACCELERATORS.

- (a) Periodic quality control checks shall be performed on all therapeutic radiation machines at intervals recommended by the manufacturer or by recognized national or international organizations.

Note: An acceptable reference is "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," AAPM Report No. 46, American Association of Physicists in Medicine, April, 1994.

- (b) Quality control checks shall include determination of central axis radiation output and a representative sampling of periodic quality control checks according to recommendations of national or international organizations. Representative sampling shall include all referenced periodic quality control checks in an interval not to exceed 14 consecutive calendar months.

Note: An acceptable reference is "Comprehensive QA for Radiation Oncology Report of AAPM Radiation Therapy Committee Task Group 40," AAPM Report No. 46, American Association of Physicists in Medicine, April, 1994. The publication may be consulted at the Department of Health and Family Services, Radiation Protection Section, 1 West Wilson St. Room 150, Madison WI 53702-0007. AAPM reports may be obtained from Medical Physics Publishing, 4513 Vernon Blvd., Madison WI 53705-4964 or ordered from their website: www.medicalphysics.org.

(16) OPERATING PROCEDURES.

- (a) A therapeutic radiation machine may not be left unattended unless secured.
- (b) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices or other means recommended by a physician shall be used.
- (c) An x-ray tube housing assembly may not be held by a person during operation unless the assembly is designed to require holding and the peak tube potential of the system does not exceed 50 kV. In these cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV.
- (d) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
- (e) No person other than the patient may be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any person, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of s. HFS 157.22 (1).
- (f) A registrant shall promptly repair any system that is not operating properly.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02.

HFS 157.86 Registration of radiation machine facilities.

(1) REGISTRATION FEES.

- (a) An annual registration fee shall be levied for each site registration under this section, according to the following schedule:
 1. For a site having an ionizing radiation installation serving physicians and clinics, osteopaths and clinics, chiropractors or hospitals, the fee shall be \$50 for each site and \$50 for each x-ray tube.
 2. For a podiatric or veterinary site having an ionizing radiation installation, the fee shall be \$50 for each site and \$50 or each x-ray tube.
 3. For a dental site having an ionizing radiation installation, the fee shall be \$50 for each site and \$35 for each x-ray tube.
 4. For an industrial, school, research project or other site having an ionizing radiation installation, the fee shall be \$50 for each site and \$50 for each x-ray tube.

5. An additional fee of \$50, regardless of the number of devices, shall be required for each registration whenever the annual fee for renewal is not paid prior to the expiration of the registration.
6. A change of ownership requires re-registration and fees paid by the new registrant.
7. Any change in registration information shall be submitted to the department within 30 days after the change takes place. No fee is required for recording changes in registration information.
8. Manufacturing, testing or servicing facilities shall be considered as one x-ray tube for registration purposes.
9. Electron microscopes and extremity bone densitometers are exempt from registration fees after the initial registration.

(2) EXEMPTIONS. The following items are exempted from the requirements of this section:

- (a) Electronic equipment that produces radiation incidental to its operation for other purposes, such as x-rays from radio or television transmitter high voltage tubes.
- (b) Radiation machines in transit or storage.
- (c) Domestic television receivers and computer monitors.

(3) RECIPROCAL RECOGNITION OF OUT-OF-STATE RADIATION MACHINES.

(a) Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring the machine into the state shall give written notice to the department by mail or facsimile at least 48 hours before the machine is to be used in the state. The notice shall include all the following information:

1. The type of radiation machine.
2. The nature, duration and scope of intended use.
3. The exact location or locations where the radiation machine is intended to be used.
4. States in which the machine is registered.

(b) If, for a specific case, the 48-hour notice period would impose an undue hardship on the person, that person may apply to the department for verbal permission to proceed sooner.

Note: The department may be contacted by phone at 608-267-4784 or facsimile at 608-267-4799.

(c) The person in control shall do all the following:

1. Comply with all applicable rules of the department.
2. Supply the department with other information as the department requests.
3. Not operate within the state on a temporary basis in excess of 30 calendar days per year without obtaining a Wisconsin registration.

History: CR 01-108: cr. Register July 2002 No. 559, eff. 8-1-02; CR 06-021: am. (1) (a) 1. to 5. Register October 2006 No. 610, eff. 11-1-06.